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October 28, 1998

Mr. James R. Rodeheaver
Branch Chief
Processed Products Branch
Fruit and Vegetable Programs
Agricultural Marketing Service
U.S. Department of Agriculture
STOP 0247, P.O. Box 96456
Washington, D.C. 20090

Dear Mr. Rodeheaver:

I am writing this letter in regards to the USDA's "Qualified Through Verification" Program (QTV). This program is proactive and preventative in nature, thereby helping to efficiently eliminate or reduce food hazards found in fresh fruits and vegetables. The USDA (QTV) shield on food products is an assurance to consumers that they are buying safe, nutritious products.

Food-borne illnesses are appearing across this nation in increasing amounts, underscoring the need for programs such as the QTV to reassure the American public of the safety of their fresh fruit and vegetable products. The "Quality Through Verification" program is a worthwhile one that should be continued by the USDA, in their pursuit of increasing food safety awareness.

Thank you very much for your consideration of my request.

Sincerely,

Thomas W. Ewing

Thomas W. Ewing
Member of Congress

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October 27, 1998

Mr. James R. Rodeheaver
Branch Chief
Processed Products Branch
Fruit and Vegetables Programs
Agricultural Marketing Service
U.S. Department of Agriculture
STOP 0247 -- P.O. Box 96456
Washington, D.C. 20090-6456

Dear Mr. Rodeheaver:

My purpose in writing is to take advantage of the opportunity expressed in the *Federal Register*, Volume 63, No. 172, page 47220 dated September 4, 1998 to comment on the U.S. Department of Agriculture's "Qualified Through Verification" (QTV) program.

Based on the experiences of Handi-Pak Foods, Inc. of Kankakee, Illinois, which has participated in the QTV pilot program, the Qualified Through Verification program seems to be worthy of expansion throughout the fresh-cut produce industry. Handi-Pak Foods is the leading fresh-cut produce business in my area.

According to Handi-Pak Foods, the QTV program has encouraged the creation of a valuable partnership relationship between fresh-cut fruit and vegetable processors and the Fruit and Vegetable Division of the USDA's Agricultural Marketing Service. The cooperative nature of this effort has resulted in emphasis being placed on taking proactive and preventative steps to reduce or even eliminate food hazards and protect the health of consumers.

If the QTV program involving Handi-Pak Foods can be successfully replicated on an industry-wide basis, the ultimate result should be a significant increase in the level of confidence which U.S. consumers have in the quality of vegetable and fruit products found in the stores.

In particular, the use of the QTV modification of the widely known and well respected USDA shield seems to be providing a boost both to the marketing efforts of the fresh-cut produce industry and also to the confidence of consumers.

While I have little firsthand information about the QTV program, I am quite familiar with the Handi-Pak Foods company and its very capable management. Their high level of satisfaction with the Qualified Through Verification pilot program -- which they have been using for several years -- causes me to believe it has considerable merit. Expansion throughout the industry should be seriously considered.

Thank you for the opportunity to comment on this matter. I would very much appreciate your keeping me informed about the status of this worthwhile effort to increase the quality of the fruit and vegetable products available to our nation's consumers. This information should be sent to Reed Wilson, District Director on my staff, in my Joliet, Illinois District congressional office.

Sincerely,

Jerry Weller
Representative in Congress
11th District, Illinois

cc: Mr. Warren Ouwenga

October 29, 1998

Mr. James R. Rodeheaver,
Office of the Branch Chief
Processed Products Branch, Fruit and Vegetable Programs
Agricultural Marketing Service
U.S. Department of Agriculture
STOP 0247, P.O. Box 96456
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Dear Mr. Rodeheaver,

We appreciate the opportunity to provide comments on the QTV Program, July 1998 draft. We have several concerns about the program which involve the following areas:

- False sense of security for less knowledgeable producers
- Perception of safety with consumers
- Hazard Analysis and HACCP principles
- Competitive flora and *C. botulinum*
- Microbiological testing
- Audit Policies
- Quality vs. Food Safety

We agree that the 3rd party HACCP verification program portion of QTV is as useful as any other (e.g. AIB). However, given that the QTV Shield is issued by a federal agency, the QTV qualification and Shield can be misinterpreted (especially by lower tier producers) as an indication that the producer has done a comprehensive hazard analysis that addresses all product design and production food safety issues.

Because of the complex issues regarding the food safety of ALL fresh cut produce products (present and future) we believe the current USDA QTV program and Shield for this emerging industry is inappropriate and potentially counterproductive to food safety. We especially do not agree with the shield because it can be misinterpreted by the producer, retail/foodservice buyer and consumer as a guarantee of Food Safety.

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Food Safety and the QTV process (today) are not synonymous. As admitted in the most recent QTV draft, QTV does not do (or require) challenge tests with products packaged in low oxygen (that could harbor *Clostridium botulinum*). Therefore, unless every fresh cut producer does a thorough hazard analysis, their HACCP programs could be inadequate but still carry the QTV Shield of "validation."

> "AMS has not established any protocols to identify products at risk to support the growth of *C. botulinum* under low oxygen packaging." (correspondence to IFPA)

The Shield should not be used unless all reasonable scientific facts are in place to show that a given fresh cut category (or product) presents risks that are as low as reasonably achievable (such as with low oxygen packaged lettuce salads) when the cold chain is broken (especially under gross temperature abuse by the consumer).

Since the QTV program does not require a comprehensive hazard analysis that includes challenge testing where appropriate, the QTV Shield could be used on unsafe products causing potential injury to customers and the entire industry.

Audit System

There are fundamental concerns about the audit system. These concerns result in the use of the shield with potential or known food safety hazards:

1. A Level IV processor can have 3-4 Serious Deficiencies. Level III allows 1-2 Serious Deficiencies. Based upon the definition of 'Serious' ("A deviation from QTV plan requirements such that maintenance of safety, and economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, branded product") it seems inappropriate to approve a facility at level IV or level III.

2. The Level V rating is the result of one critical deficiency ("A deviation in QTV plan requirements such that the maintenance of the safety is absent; will result in unsafe product.") The facility then has 30 days to reach level IV prior to AMS withdrawing its service and the use of the QTV mark.

   This means that packages are using the shield for 30 days while a critical deficiency has been found. Facilities can continue to have one critical deficiency and remain in the program if these occur less than twice in a six-month period.

HACCP Principles

There are fundamental flaws in the HACCP principles as they are presented in the QTV program.

1. The sample HACCP program does not include all of the appropriate steps in the hazard analysis. It does not address the risk and likelihood of hazards. The hazards should be assessed to determine if they are covered in pre-requisite programs, or if they are CCPs.

2. HACCP is product, process and facility-specific, therefore it is not appropriate for AMS to determine if a company's CCPs are adequate (p. 21).

3. In addition, the critical limits indicate an 'operating range,' CCPs should not have a range. (p. 22)

4. Some of the preventative measures are actually pre-requisite programs.

5. There is still a lack of separation between quality and food safety. The examples of hazards include quality issues: signs of temperature abuse, physical damage, etc.

Microbiological Testing

AMS has removed the requirement for finished product testing, however, they are specifying which areas microbiological testing programs should address (p. 11):

> "...a microbiological testing program shall, at least, address the following areas:
> Incoming product testing;
> Equipment and environmental testing; and
> Corrective actions when microbiological testing for targeted microorganism prove positive for possible contamination.
>
> Finished product testing is optional if in-coming and environmental microbiological testing procedures are acceptable to AMS."

It is an individual company's decision to determine the appropriate microbial testing procedures. The value of incoming product testing is questionable. The focus should be on preventive raw product food safety programs and vendor requirements, not random testing.

> "General Consideration:...Companies producing these products should be continuously monitoring the microorganisms present on the produce, before, during and after processing to determine background information about known pathogens such as *Listeria, Shigella, Salmonella, E. coli* and respective range counts for total coliforms, etc." (p. 51)

AMS will periodically sample product for generic E. coli. If these results are positive, the company is expected to take prompt corrective action to "protect the public health and well-being from products that present a risk" (p. 12) Generic E. coli is an indication of possible fecal contamination. Only pathogenic E. coli present a risk to public health.

Competitive Microflora

The normal, harmless microflora on vegetables is an important component of packaged fresh-cut salad safety because they cause spoilage prior to potential toxin production from the rare event of *C. botulinum* contamination. The QTV program's July draft does not indicate an understanding of this principle.

> "…One of the first steps in minimizing the microbial load is to receive and use product of the best condition" (p. 12)
>
> "…Fresh-cut fruits and vegetables, whether vacuum-packed or in modified atmosphere (MA), are expected to have no known disease-producing, or pathogenic microorganisms, and substantially reduced microflora" (p. 51)

In addition, there is a large amount of variability in total plate counts on raw produce, therefore, there is doubt as to what value these data would add.

In conclusion, since there are no provisions for effective hazard analysis, there are issues with HACCP principles, audit procedures, and an understanding of the normal, harmless microflora, we believe that the Qualified through Verification program will not be effective in maintaining and enhancing food safety for the fresh-cut packaged food industry.

Sincerely,

Joan Rosen

Joan Rosen
Director, National Food Safety
and Regulatory Affairs

2 academia

The University of Georgia

College of Agricultural and Environmental Sciences
Center for Food Safety and Quality Enhancement

September 21, 1998

Dr. Eric Forman
Associate Deputy Administrator for
Fruit and Vegetable Programs
U. S. Department of Agriculture
1400 Independence Avenue, SW
STOP 0234
Washington, DC 20250-0234

Dear Dr. Forman:

I received from Dr. Enrique Figueroa a draft copy of the AMS "Qualified Through Verification" Program for the fresh-cut produce industry, with a request to provide to you my thoughts about the program.

I commend that AMS for developing such a program for the fresh-cut produce industry. It is a major step forward to enhancing the safety of fresh-cut produce products. I have several suggestions for improvement of the document, most of which are small but important. However, there is one very major concern that needs attention as it is critical to the integrity and success of the overall QTV program. This relates to the critical control point (CCP) component of the program. I am troubled by the QTV's interpretation of CCP's, which will in the end, be either the strength or weakness of the program. Specifically, a CCP must either eliminate a hazard or prevent a hazard from occurring. If a hazard already exists, such as the presence of *E. coli* O157:H7 on product ingredients, then employing a "control point" like refrigeration will not make the product safe. Hence, refrigeration, although important in preventing pathogens from growing, is not a CCP if low populations of infectious bacteria are present and can cause illness. Providing a kill step, such as the use of chlorination, could be a CCP.

I offer the following specific comments for your consideration:

(1) P.1 lines 7 and 13. Change "effectiveness" to "suitability." Simply reviewing a company's HACCP plan does not verify the effectiveness of the plan.

(2) P.1 line 15. Change "confirm" to "verify."

(3) P.1. Between lines 29-30. Insert "Implementation of a HACCP Program with Suitable Critical Control Points"

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(4) P.4 line 14. Add to "Control Point" definition ...but does not eliminate a hazard.
- There needs to be a clear understanding by the fresh-cut produce industry and by AMS personnel of the meaning of control points and critical control points.

(5) P.8 line 13. Change "all of the documented critical control points" to "the appropriate critical control points."

(6) P.10 lines 18-19. Simply accelerating the audit schedules for facilities that fall to Level V or receive a critical deficiency is too lenient. What if a serious pathogen is found in a product? This would suggest that the HACCP plan may be defective or is not properly implemented. More needs to be done than simply accelerating the audit schedule. Immediately withdrawing QTV accreditation seems to be a more appropriate action for such a deficiency.

(7) P.10 line 20. Allowing a facility 30 days to come into compliance to Level IV is too long if a facility has critical deficiencies. Such relaxed compliance standards minimize the value of the QTV program.

(8) P.11 line 8. Change "inspection" to "testing."

(9) P.11 lines 11-12. Allowing a facility to drop to Level V twice in a 6-month period before withdrawing QTV accreditation is incredibly lax and minimizes the value of the QTV program.

(10) P.11 line 29. Finished product testing should not be optional unless the HACCP plan has a verified CCP that kills at least 3 logs (and preferably 5 logs) of *Salmonella*. Otherwise, finished product testing is needed to verify the efficacy of the process.

I would suggest that the AMS provide guidance regarding the need for verified kill steps and finished product testing. AMS should establish minimum tests to be performed and maximum performance standards. Verification should include *Salmonella* end-product testing and *Listeria* testing of equipment and the environment.

(11) P.12 line 14. I trust that generic *E. coli* will be enumerated. If so, this should be so stated. Also, there is a need to indicate the frequency of sampling and testing.

(12) P.12 line 30. Who will qualify the AMS review team? There needs to be a common understanding by review team members and the fresh-cut produce industry regarding the definition of a critical control point and control point, and the composition of an acceptable HACCP plan.

(13) P.18 Figure 4. It is highly likely that many of the CCP's noted in this figure are control points (CP's), not CCP's.

(14) P.19 lines 31-33. This statement, "This hazard process identifies hazards that must be eliminated, reduced to a safe level or prevented in order to present a safe product," is the basis for defining CCP's. If a control measure does not meet the above criteria, it is not a CCP but rather is a CP. For example, if *E. coli* O157 or *Salmonella* is present on produce, refrigerating the product at 32 to 40°F will not eliminate the hazard. Hence, refrigeration is a CP, not a CCP.

(15) P.19 line 36. Delete "protein" and add "allergens."

(16) P.20 lines 6-9. Decomposition and physical damage are not "physical hazards." They are not hazards but rather GMPs.

(17) P.20 line 12. Add "allergens."

(18) P. 20 lines 16-25. Only the metal detector is a control point among those listed. The rest are potential locations of CPs, but are not CPs.

(19) P.20 lines 31-32. This sentence is redundant; CCP's are control measures.

(20) P.21 lines 2-5. These two bullet points are redundant.

(21) P. 21 lines 9 and 11. Change CCP's to CP's.

(22) P.22 lines 10, 13, 20 and 27. Add "or CP" following "CCP."

(23) P.26 Figure 6. The information provided in this figure is not illustrative of a Critical Control Point. The two descriptions under preventative measures and critical limit describe control points, not critical control points.

(24) P.26 line 21. Is holding produce at less than 32°F a hazard? I cannot identify a reason for considering frozen produce to be a safety hazard.

(25) P.27 Figure 7. The information provided in this figure is not illustrative of a Critical Control Point. The description under preventative measure and critical limit describe control point, not a critical control point.

(26) P.27 lines 9 and 15. Holding produce at less than 32°F does not result in a safety hazard. This should not be included in a HACCP plan.

(27) P.29 lines 22-23. Finished product testing may be needed for verification so would not be optional.

(28) P.29 Add line 33. Add "Testing ingredients and incoming materials."

(29) P.29 last line. Add "This can necessitate end-product testing."

(30) P.35 "Procedures" section. Change "Preventive measures not followed" to "Critical Control Points not followed" and move box from major to critical.

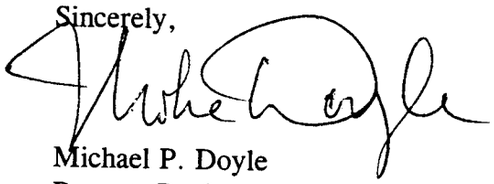
(31) P.35 "Procedures" section. Add "Control Points not follows" and insert box under "serious" column.

(32) P.51 lines 28 and 29. "Quality" should be deleted; quality is not a microbiological hazard. Only safety issues should be addressed.

(33) P.52 Microbiological tests. I would suggest eliminating coagulase-positive *Staphylococcus*, psychrotrophic plate count, Geotrichum count, and yeast and mold count as these are not relevant to safety hazards associated with fresh-cut produce. Also, insect & rodent filth is not a microbiological assay and should be removed from the microbiological section.

Good luck with the QTV program. If well designed and properly implemented, it will be a real asset to the industry and a major benefit to public health.

Sincerely,



Michael P. Doyle
Regents Professor and Director

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cc: Dr. Enrique Figueroa